

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION OPIATE  
LITIGATION**

This document relates to:

*Jennifer Artz, et al. v. Endo Health Solutions Inc., et al.*  
Case No. 1:19-OP-45459

*Michelle Frost v. Endo Health Solutions Inc. et al.*  
Case No. 1:18-OP-46327

*Salmons v. Purdue Pharma L.P., et al.*  
Case No. 1:18-OP-45268

**MDL No. 2804**

**Case No. 17-md-2804**

**Judge Dan Aaron Polster**

**DEFENDANTS' OPPOSITION TO NAS PLAINTIFFS'  
MOTION FOR RECONSIDERATION**

Plaintiffs' motion for reconsideration of the Court's order denying class certification fundamentally misconstrues both the order itself and the governing case law.<sup>1</sup> Plaintiffs fail to demonstrate that the Court committed any error, much less clear error or a manifest injustice; in fact, their motion reinforces that the Court's decision was correct. Among other points, the Court correctly (1) examined the evidence in the record to determine that some proposed class representatives were not even members of the classes; (2) found that the classes were not ascertainable due to class definitions that required, at a minimum, expert analysis of hundreds of pages of medical records to determine whether each potential class member qualified for

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<sup>1</sup> Several defendants named in this litigation are not subject to the Court's personal jurisdiction. This opposition is filed subject to and without waiving all defenses, including but not limited to lack of personal jurisdiction, failure of service of process, and ineffective service of process.

inclusion; and (3) found that the proposed classes did not meet Rule 23(a)'s typicality requirement because their claims presented numerous distinct factual and legal questions. The Court's findings and reasoning with respect to adequacy and typicality were more than sufficient to support its ruling, and indeed also support a determination that Plaintiffs have failed to meet most of the other requirements of Rule 23.

Much of Plaintiffs' motion for reconsideration seeks "reconsideration" of rulings the Court did not even make, reflecting fundamental misunderstandings of the Court's decision. The Court did not, for example, purport to expand the class definition to require a showing that birth mothers were addicted to opioid medications, Pls.' Mot. for Reconsideration ("Mot"), dkt. 3630, at 7-8, 11-12; rather, it found that [REDACTED]

[REDACTED] created a number of critical differentiating factual and legal issues for the claims of class members. Opinion & Order, dkt. 3623, at 24-25. Nor did the Court make any findings that relied on the timing of postnatal weaning. Mot. at 4-5. It is difficult to understand the source of Plaintiffs' impression that any such findings were made, but it appears to have come from the Court's finding (based upon undisputed evidence) that two of the children of proposed class representatives received opioid medications for *completely different* purposes later in life — a disqualifying fact under Plaintiffs' own class definitions.

The remainder of Plaintiffs' arguments misapprehend the governing law and would be of no avail even absent the heightened standard that applies to a motion for reconsideration. For these reasons, Plaintiffs' motion should be denied.

### **LEGAL STANDARD**

As this Court has previously noted, *see* dkt. 3499, motions for reconsideration are justified only when there is "a need to correct a clear error or prevent manifest injustice."

*Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004). A

motion for reconsideration is properly rejected unless it “either calls . . . attention to an argument or controlling authority that was overlooked or disregarded in the original ruling, presents evidence or argument that could not previously have been submitted, or successfully points out a manifest error of fact or law.” *Davie v. Mitchell*, 291 F. Supp. 2d 573, 634 (N.D. Ohio 2003). No such showings have been made — or even attempted — here.<sup>2</sup>

## ARGUMENT

### **I. The Court Correctly Determined that Two Proposed Class Representatives Were Not Class Members.**

Plaintiffs argue that the Court should reconsider its denial of class certification because it purportedly rejected Dr. Anand’s supplemental expert testimony and misconstrued evidence that two of the class members’ children had been “pharmacologically weaned” with opioid medications after birth. Plaintiffs’ argument is factually and legally wrong.

The Court was required to conduct a “rigorous analysis” in order to determine whether the mandatory Rule 23 requirements had been satisfied. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350-51 (2011). That analysis properly includes resolution of factual and legal questions even where such questions may overlap with the merits of Plaintiffs’ claims. *Id.* at 351. Plaintiffs had the burden of proof on all required Rule 23 elements and failed to meet that burden. *Id.* at 350; *see also Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537 (6th Cir. 2012) (class determination must be predicated on “evidence”).

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<sup>2</sup> Plaintiffs suggest that their motion should be judged under a more lenient standard because courts may alter or amend decisions on class certification as a case progresses. Mot. at 4. However, the out-of-circuit case Plaintiffs cite — *Hargrove v. Sleepy’s LLC*, 974 F.3d 467 (3d Cir. 2020) — is inapposite because it does not address a motion for reconsideration. At issue in *Hargrove* was a *renewed* motion for class certification in which the plaintiff had amended its class definition to be “narrower and clearer” so as to cure the failings in its original motion. *Id.* at 476-77. Here, Plaintiffs are seeking reconsideration of the Court’s ruling on their original motion, and the problems with their original motion were much more fundamental.

Plaintiffs criticize the Court for examining the factual record in conducting its Rule 23 analysis, asserting that it “unilaterally . . . reject[ed] the existence of qualified evidence,” specifically Dr. Anand’s supplemental declaration, which was submitted for the first time with Plaintiffs’ reply brief. Mot. at 4. This is false on both the law and the facts. As *Dukes* held, the Court is required to perform a critical review of the record to determine if Rule 23 is satisfied, which may include evaluating expert testimony. *See Dukes*, 564 U.S. at 353-55 (disregarding expert testimony that does not satisfy Rule 23 requirements). Regardless, Plaintiffs’ argument mischaracterizes what the Court actually did.

The Court made no findings that rejected Dr. Anand’s supplemental declaration, which purported to identify the various diagnostic indicia of NAS present in the relevant children’s medical records. *See* Dkt. 3557 at 2. To the contrary, the Court considered the factual information submitted in that declaration and cited it repeatedly. *See* Opinion & Order at 5-6 & n.9.<sup>3</sup> After doing so, the Court determined that two of the three proposed class representatives did not meet the class definition. This decision did not reject any of Dr. Anand’s assertions; rather, it rested on undisputed evidence on a *different* point, opioid use later in life, that Dr. Anand did not address.

Plaintiffs’ motion for class certification excluded from “all classes” the guardians of minors treated with opioid medications after birth for reasons other than pharmacological weaning, Pls.’ Mem. in Supp. of Mot. for Class Certification, dkt. 3066-1, at 5. [REDACTED]

[REDACTED]

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<sup>3</sup> In fact, the Court would have been fully entitled to reject this declaration, which was submitted in an untimely “supplemental” report appended to Plaintiffs’ reply brief and could have been disregarded for that reason alone. *See* Defs.’ Surreply, dkt. 3567, at 5-7; Opinion & Order at 5 n.9.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs do not challenge or rebut this evidence. Even Dr. Anand's second supplemental declaration, submitted improperly with Plaintiffs' motion for reconsideration, does not address it; that disclosure largely just provides citations to particular medical records as support for Dr. Anand's prior opinions.<sup>4</sup> Instead, Plaintiffs complain only that the Court should not have made a finding about the timing of pharmacological weaning. Since the Court made no such finding, these arguments are irrelevant.

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<sup>4</sup> A motion for reconsideration may consider new evidence only where that evidence is "newly discovered" — that is, "previously unavailable." *See GenCorp, Inc. v. Am. Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999). Dr. Anand's new declaration analyzes medical records that were, at the latest, available to Plaintiffs at the time they submitted their reply brief in support of their motion for class certification. Accordingly, it does not constitute "newly discovered evidence" under the reconsideration standard. *See, e.g., Ne. Ohio Coalition for the Homeless v. Brunner*, 652 F. Supp. 2d 871, 881 (S.D. Ohio 2009) (rejecting motion for reconsideration based on declaration that "could have (and should have)" been secured earlier).

[REDACTED]

## **II. The Court Correctly Found that Plaintiffs' Proposed Classes Were Not Ascertainable.**

Plaintiffs seek to challenge three aspects of the Court's finding on ascertainability: that a medical diagnosis of NAS is not reasonably ascertainable, Mot. at 8-9; that the element of legal guardianship is also not reasonably ascertainable, Mot. at 6-7; and that ascertainability poses a bar to certification of their classes, Mot. at 10. Plaintiffs' arguments fail on all three points.

Plaintiffs' argument that the Court may easily ascertain whether an infant has been "medically diagnosed with NAS" fails for multiple reasons. Most fundamentally, the evidence Plaintiffs proffer to support this argument actually proves the Court's point: Plaintiffs' class definition relies not on "objective medical criteria," but rather on "diagnostic indicia" that would require extensive expert analysis. Dkt. 3623 at 14. Plaintiffs' motion for reconsideration again asks that the Court determine class membership not by looking for an actual contemporaneous diagnosis of opioid-related NAS, but rather by conducting a "records review for . . . criteria" that their expert concludes would have permitted such a diagnosis to be made. Mot. at 9.

Plaintiffs *assert* that performing this medical review would be "hardly more difficult" than the analysis of class membership required in a securities class action. *Id.* But the evidence they have offered on their class representatives is to the contrary. Dr. Anand has now submitted two supplemental declarations, the second containing 740 pages of appendices, purporting to demonstrate that the children of a small number of proposed class representatives met the criteria for NAS. *See* Anand Reconsideration Declaration, dkt. 3632. Dr. Anand's latest declaration, submitted in support of Plaintiffs' motion for reconsideration, cites dozens of pages from the children's medical records in an attempt to piece together various prescriptions, test scores, and handwritten notes by doctors. In short, Dr. Anand's work demonstrates that proving this component of class membership requires precisely the "individualized assessment" that

precludes class certification on multiple grounds, including ascertainability. *See Stewart v. Cheek & Zeehandelar, LLP*, 252 F.R.D. 387, 391 (S.D. Ohio 2008).

Moreover, Plaintiffs' argument still ignores the fact that their own class definition requires that the infant be medically diagnosed with *opioid-related* NAS. Mem., dkt. 3066-1, at 4-6. As Defendants' experts testified, and Plaintiffs have not refuted, NAS may be caused by substances other than opioids, and an NAS diagnosis alone does not therefore establish this element of Plaintiffs' class definition. Ex. 3, Wright Rep. at 2.<sup>5</sup>

With respect to guardianship, Plaintiffs again misconstrue the Court's order. As the Court noted, given the length of time over which relief would have to be administered for Plaintiffs' proposed class, guardianship of the children who are the source of the entitlement to relief would likely fluctuate. *See* Defs.' Opp. to NAS Pls.' Mot. for Class Certification, dkt. 3536, at 15 [REDACTED]

[REDACTED] As the Court rightly pointed out, this is a serious problem in this case, where the relief requested would implicate "a period of many years, perhaps decades." Dkt. 3623 at 13. Instead of addressing the problem the Court identified, or refuting any of the sources the Court cited, Plaintiffs simply reiterate their prior arguments and assert that the Court clearly erred by not accepting them. The Court did not err; a shifting class whose proposed relief would span

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<sup>5</sup> Even if Dr. Anand's second supplemental declaration were properly considered on a motion for reconsideration — and it is not — it would provide little help to Plaintiffs on this issue. [REDACTED]

[REDACTED]

decades is not readily ascertainable and could not be practicably managed. *See McElhaney v. Eli Lilly & Co.*, 93 F.R.D. 875, 878 (D.S.D. 1982); Fed. R. Civ. P. 23(b)(3)(D).

Finally, Plaintiffs argue that the Court erred because ascertainability should not be a requirement for their proposed Rule 23(b)(2) class. In the ruling Plaintiffs cite, *Cole v. City of Memphis*, 839 F.3d 530 (6th Cir. 2016), the Sixth Circuit relied in large part on the proposition that class members in a Rule 23(b)(2) class should not need to receive notice or be identified in order for the injunctive remedy to be carried out. *See id.* at 541-42. The Court went on to note: “The main purpose of a (b)(2) class is to provide relief through a single injunction or declaratory judgment. ‘Because the focus in a (b)(2) class is more heavily placed on the nature of the remedy sought, and because a remedy obtained by one member will naturally affect the others, the identities of individual class members are less critical in a (b)(2) action than in a (b)(3) action.’” *Id.* at 542 (quoting *Shelton v. Bledsoe*, 775 F.3d 554, 561 (3rd Cir. 2015)).

Here, Plaintiffs are seeking certification under both Rule 23(b)(2) and 23(b)(3) to pursue a remedy that *would* require the identification of individual class members and provision of notice to them so that they could be enrolled in Plaintiffs’ proposed medical monitoring program, which would include not only specific testing and services being provided to class members’ children but also funding on an individual level for medical expenses. *See* Pls.’ Mem., dkt. 3066-1, at 37. Unlike in the situation contemplated in *Cole*, therefore, there can be no question that objective criteria would be needed to allow identification of class members. In short, *Cole* permits only one of two conclusions here: either certification is simply not available under Rule 23(b)(2) for a class, such as this one, that is not seeking the unitary injunctive relief the Sixth Circuit described or, at a minimum, *Cole*’s finding on ascertainability is limited to classes that

are seeking such unitary relief.<sup>6</sup> *See Jamie S. v. Milwaukee Public Schools*, 668 F.3d 481, 493-96, 498-99 (7th Cir. 2012) (holding that proposed class seeking relief requiring notice to class members and participation in individualized remedial program had to be ascertainable and could not be certified under Rule 23(b)(2)). Either way, *Cole* does not permit certification of a class in this case, in which the relief sought could not be carried out without identifying class members.

**III. The Court Correctly Found that the Claims of Plaintiffs' Proposed Class Representatives Were Not Typical of the Class.**

Plaintiffs hurl numerous confused accusations at the Court and Defendants related to the Court's finding that Plaintiffs had not demonstrated typicality. None demonstrates any error (much less a manifest error) of fact or law.

**A. The Court's finding of a lack of typicality is supported by its discussion of illicit opioid use.**

One of Plaintiffs' primary complaints, about the role and significance of maternal addiction, again completely misapprehends the Court's ruling. Addiction is not an element of Plaintiffs' defined class, nor (contrary to Plaintiffs' assertion, *see* Mot. at 7-8) did the Court make it one. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>6</sup> In fact, given that Plaintiffs are seeking extensive *monetary* relief, certification would not have been available under Rule 23(b)(2) in any event. *See Dukes*, 564 U.S. at 360-61; Defs.' Opp. at 45-47.

[REDACTED]

[REDACTED]

[REDACTED] See Opinion & Order at 24-25.

Since Plaintiffs are simply wrong in asserting that the Court treated addiction as an additional required element of the class definition, their arguments for why such treatment would have been improper (Mot. at 7-8, 11) are irrelevant and provide no basis for reconsideration.

Plaintiffs' remaining arguments about the Court's finding on typicality once again instead prove the Court's point. Plaintiffs cite *Newberg on Class Actions* with respect to typicality: "[A] plaintiff's claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the *same legal theory*." Mot. at 11 n.16 (citing 1 *Newberg on Class Actions*, Section(s) 3-13, at 3-76) (emphasis added). Then, when describing their legal theories against Defendants, Plaintiffs characterize them as follows:

Plaintiffs' primary contention is that opioids should have never been marketed or distributed to women who were pregnant, or who could become pregnant, and that liability flows from this most basic premise. And, of course, Plaintiffs contend that Defendants should have controlled their drugs, such that no secondary, diversionary market existed, and a pregnant woman could not have obtained opioids from that source either.

Mot. at 12. These are distinct theories of liability subject to entirely different types of proof and defenses. [REDACTED]

[REDACTED]

[REDACTED]

**B. The Court’s analysis of the typicality requirement was proper.**

Plaintiffs complain that the Court did not analyze every element of their legal claims to separately assess typicality for each element. But no such analysis was required. As other courts in this district have noted, the proper scope of inquiry with respect to typicality is “whether, despite the presence of common questions, each class member’s claim involves so many *distinct* factual or legal questions as to make class certification inappropriate.” *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 303 (N.D. Ohio 2007) (citation omitted). Plaintiffs have the burden of establishing that the claims of the class representatives present few, if any, distinct questions that must be decided in addition to the issues claimed to be common. *See id.* at 303, 308-09 (finding typicality wanting despite several common issues). If the Court finds that they have failed to carry this burden, as the Court did here, the analysis properly ends.

Nor is there any merit to Plaintiffs’ arguments that the Court’s analysis was inconsistent with its (or other courts’) holdings in other cases. The negotiation class was certified strictly for a non-litigation context, with an explicit warning that its findings should not be cited in other contexts. That class consisted of a group of cities and counties, not the individuals involved in Plaintiffs’ proposed classes. Moreover, as the Court observed in its ruling here, the certification of the negotiation class has been reversed. *In re: Nat’l Prescription Opiate Litig.*, 976 F.3d 664 (6th Cir. 2020). Even if this Court had not already disclaimed any precedential value for that decision, therefore, the point would now be moot. *See Barkovic v. Att’y Grievance Comm’n*, 289 F. Supp. 3d 833, 844 (E.D. Mich. 2017) (“A decision that has been vacated has no precedential authority whatsoever.” (quoting *Durning v. Citibank, N.A.*, 950 F.2d 1419, 1424 n.2 (9th Cir. 1991))).

Plaintiffs’ citation to Judge Breyer’s decision in *City and County of San Francisco v. Purdue Pharma L.P.*, 2020 WL 5816488 (N.D. Cal. Sept. 30, 2020), is similarly flawed — and

Plaintiffs’ statement that Judge Breyer found “Rule 23 treatment was appropriate,” Mot. at 14, is simply false. Judge Breyer denied in part and granted in part the motions to dismiss the City of San Francisco’s complaint. The City is, of course, not an NAS plaintiff, and while Judge Breyer allowed the City’s UCL claim to proceed, that claim had nothing to do with pregnancy or the provision of opioid medications to pregnant women. *See id.* at \*46. Even more importantly, the cited decision had *nothing* to do with Rule 23; no class claim was asserted in the San Francisco complaint; and Judge Breyer’s lengthy decision says nothing about class actions. As Defendants demonstrated in their opposition to Plaintiffs’ motion for class certification, the UCL claims of *these* Plaintiffs present numerous individualized issues, and courts have found that such individualized questions can render class certification of false marketing claims inappropriate. *See* Defs.’ Opp. at 51-52 (citing *Davis-Miller v. Automobile Club of S. Cal.*, 134 Cal. Rptr. 3d 551, 562, 564-66 (Cal. Dist. Ct. App. 2011)). Judge Breyer’s decision is not to the contrary.

Plaintiffs’ remaining arguments related to typicality are similarly without merit:

- Plaintiffs broadly claim that the Court erred because claims brought under some of the state laws they invoke are “routinely certified for Rule 23 treatment under state law.” Mot. at 14-15. Plaintiffs’ burden was to establish that *their particular claims* are suitable for class treatment. *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 275 (2014). It is irrelevant that different classes with different claims brought under the same state laws have been certified. In fact, the vast majority of proposed personal injury classes are *not* certified due to the necessity for individualized proof. Defs.’ Opp. at 19.
- Plaintiffs argue that the Court incorrectly considered defenses like contributory negligence when Defendants have not yet submitted responsive pleadings setting out their affirmative defenses. Mot. at 11, 13. But the Court did not rest its decision on any affirmative defenses.<sup>7</sup> Rather, it examined elements of Plaintiffs’ claims, like Defendants’ liability and causation, on which *Plaintiffs* bear the

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<sup>7</sup> This argument appears to rest on Plaintiffs’ misapprehension that the Court required addition of the birth mother as an additional requirement element of the class definition. It did no such thing. *See* pp. 4-5, *supra*.

burden of proof, and determined that those elements raised a sufficient number of distinct questions to render Plaintiffs' proposed representatives not typical.

**IV. Plaintiffs' Motion for Reconsideration Does Not Challenge the Fundamental Bases of the Court's Holding.**

Plaintiffs' motion for reconsideration does not address numerous independent bases for the Court's order that alone would have been sufficient to support its decision, as class certification must be denied if Plaintiffs have failed to meet their burden with respect to *any* of the required elements of Rule 23.<sup>8</sup> *See* Opinion & Order at 8 (collecting cases).

Plaintiffs' motion does not, for example, contest several of the grounds for the Court's holding on typicality: "that the conduct of each Defendant toward each class-member varies across the class," Opinion & Order at 25 n.33; that the need for medical monitoring as a remedy does not establish typicality for Plaintiffs' claims, *id.* at 24; and that Plaintiffs' unsupported allegations of "conspiracy" cannot generate typicality, *id.* at 25. Plaintiffs' motion identifies no manifest errors of fact or law on any of these points.

Furthermore, the findings and analysis in the Court's decision would also have supported findings adverse to Plaintiffs on most of the other Rule 23 requirements. For example, Plaintiffs' only arguments for the proposition that commonality was satisfied were (1) that an appropriate medical monitoring protocol was a common question; and (2) the reasoning of the negotiation class order applied to certification of Plaintiffs' proposed classes. Dkt. 3066-1 at 27-28. Each of these points was rejected by the Court in its findings on typicality, and the Court's reasoning would equally support a finding that commonality was lacking. In addition, the Court identified

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<sup>8</sup> Plaintiffs' complaint that the Court "'gave up' on the remainder of its opinion" by failing to analyze additional Rule 23 factors after determining that Plaintiffs had failed to establish typicality and ascertainability, Mot. at 2, is therefore without merit.

numerous individual issues that would need to be adjudicated in determining whether a plaintiff is a class member and/or that raise distinct factual and legal questions for typicality purposes. Those individual issues would likewise support a finding that common issues do not predominate under Rule 23(b)(3) — an element that would need to be satisfied for any class seeking monetary relief. *See In re Am. Med. Sys.*, 75 F.3d 1069, 1084 (6th Cir. 1996) (noting that predominance requirement is “more stringent” than typicality and commonality).

Similarly, the challenges the Court found in ascertaining class membership, both initially and over time, equally require the conclusion that a class action is not a superior method for adjudicating Plaintiffs’ claims due to the difficulties of managing the litigation. *See Sandusky Wellness Ctr., LLC v. ASD Specialty Healthcare, Inc.*, 863 F.3d 460, 471 (6th Cir. 2017) (finding difficulties in identifying class members, analyzed under ascertainability by district court, also demonstrated lack of superiority). And as discussed above, the Court’s findings on ascertainability would apply equally to Rule 23(b)(2)’s requirement that “final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole,” without the need to refer to individualized issues.

In sum, the flaws that the Court identified in its order denying class certification are fundamental: the class is ill-defined; the claims assert legal theories that vary across both Plaintiffs and Defendants; and a host of individualized issues would need to be decided even to determine whether an individual was a class member, much less to adjudicate that individual’s claims. The Court correctly denied Plaintiffs’ motion for class certification and should likewise deny the motion for reconsideration.

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